

IN THE CLAIMS

This listing of claims will replace all prior versions, and listing, of claims in the application:

Listing of Claims:

1. (Currently Amended) A method for obtaining interstitial fluid for diagnostic testing comprising:

(a) porating a selected area of skin to form an opening for extracting a sample comprising interstitial fluid, which sample is suitable for quantitating an analyte;

(b) collecting [a] the sample from the opening,

wherein:

(c) step (b) is enhanced by applying a vacuum to the selected area of the skin.

2. (Currently Amended) A method for obtaining biological fluid for diagnostic testing comprising:

(a) forming an opening in an area of skin suitable for extracting a sample of biological fluid suitable for measuring a characteristic of the biological fluid;

(b) extracting the sample from the opening,

wherein:

(c) at least one of positive and negative pressure is or are employed in order to enhance the extraction of the sample.

3. (Original) The method of claim 2 wherein the biological fluid comprises blood.

4. (Original) The method of claim 2 wherein the biological fluid comprises interstitial fluid.

5. (Currently Amended) A multi-layer integrated device comprising:

(a) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;

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(b) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid; and

(c) a substrate layer:

(i) disposed below the analyte sensor and

(ii) that is capable of being in contact with a processing circuit,

wherein:

(d) the receiving layer (a) is located underneath at least a portion of the substrate layer

(c) and facilitates the movement of the biological fluid to the analyte sensor (b)[;] and further
wherein said

(e) the substrate layer (c) has at least one opening therein.

6. (Currently Amended) A multi-layer integrated device comprising:

(a) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;

(b) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the sample of biological fluid;

(c) a substrate layer:

(i) disposed below the analyte sensor and

(ii) that is capable of being in contact with a processing circuit[,]; and

(d) a bottom layer[;],

wherein:

(e) the receiving layer (a) is located underneath at least a portion of the substrate
layer (c) and wherein said

(f) the substrate layer (c) has at least one opening therein.

7. (Currently Amended) An integrated device comprising:

(a) a case;

(a)(b) a pad;

(i) disposed within the case and,

(ii) capable of receiving and transporting a biological sample containing an analyte;

(b)(c) a detector;

(i) in fluid communication with the pad (b);

(ii) disposed within the case (a); and

(iii) adapted for at least one of detecting the presence and/or quantitating the concentration of analyte in the sample[,];

(iv) said mechanism detector being capable of being in contact with a display for illustrating results of the detector; and

(e)(d) a strap or adhesive tape for holding the pad to an area of skin surface,

wherein:

(e) the integrated device contains case (a) includes at least one opening suitable to allow the biological sample containing analyte to contact the pad (b).

8. (Currently Amended) The integrated device of claim 7 wherein the pad (b) contains a surfactant to facilitate transport of the biological sample containing analyte across the pad (b).

9. (Currently Amended) An integrated device for removing and testing a biological sample from the skin, said integrated device comprising:

(a) a case having a lower section having including at least one opening therein;

(b) a pad;

(i) disposed within the case (a) and

(ii) capable of collecting and transporting a biological sample containing an analyte; and

(c) a detector:

(i) in fluid communication with the pad (b);

(ii) disposed within the case (a);

(iii) adapted for determining at least one of the presence and/or quantity of the analyte[,]; ~~said detector~~

(iv) capable of being in contact with a display for the results of the detector.

10. (Currently Amended) The integrated device of claim 9 wherein the pad (b) contains a surfactant to facilitate transport of the biological sample containing an analyte across the pad (b).

11-31. (Cancelled)

32. (Currently Amended) The combination integrated fluid harvesting and analysis device of claim 64, and further comprising a sealed electrical connection to at least one of the sensor (c) and/or a probe via the sealing final means

33-37. (Cancelled)

38. (Currently Amended) An integrated fluid harvesting and analysis device, comprising:

(a) a first layer:

(i) for positioning in contact with tissue; and

(ii) having at least one opening therein;

(iii) through which poration of tissue is achieved such that at least one opening is formed in the first layer and at least one opening is formed in the tissue in fluid communication with at least one opening in the first layer;

(b) a sensor:

(i) that is positioned in fluid communication with the at least one opening [of] in the first layer[,] and the sensor being

(ii) that is responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid.

39. (Currently Amended) The device of claim 38[.]:

(a) and further comprising a second layer overlying the first layer (a)[.] and

(b) wherein the sensor (b) being is positioned between the first layer (a) and the second layer.

40-48. (Cancelled)

49. (Currently amended) The method of claim 62, and further comprising the step of forming a sealed chamber over the layer (a) and the sensor (d).

50. (Previously Presented) The method of claim 2, wherein the characteristic of the biological fluid is the concentration of glucose.

51. (Currently Amended) A method[,] for harvesting interstitial fluid from tissue and analyzing the interstitial fluid, said method comprising the steps of:

(a) porating a selected area of skin to form an opening for extracting a sample comprising interstitial fluid, which sample is suitable for quantitating an analyte;

(b) collecting the sample from the skin opening,

wherein:

(c) step (b) is enhanced by applying a vacuum to the selected area of the skin[,];

and further wherein

(d) the sample is collected in an article comprising:

(i) a pad capable of receiving an interstitial fluid the sample[;] and

(ii) a strap or adhesive tape for holding the pad to the selected area of the skin,

wherein

(e) the article contains an opening suitable to allow the sample to contact the pad; and

(e)(f) determining the amount of analyte within the sample.

52. (Currently Amended) A method for harvesting biological fluid from tissue and analyzing the biological fluid, said method comprising the steps of:

(a) providing a multi-layer integrated device comprising:

(i) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;

(ii) an analyte sensor capable of detecting the presence of the analyte or measuring the concentration of the analyte in the fluid;

(iii) a substrate layer:

(A) disposed below the analyte sensor

(B) that is capable of being in contact with a processing circuit[,]; and

(iv) a bottom layer[;];

(v) wherein:

(A) the receiving layer (i) is located underneath at least a portion of the substrate layer (iii) and wherein said

(B) the substrate layer (iii) has at least one opening therein;

(b) forming an opening in an area of skin suitable for extracting a sample of biological fluid suitable for measuring a characteristic of the biological fluid;

(c) extracting the sample from the skin opening in the area of skin; and

(d) introducing the biological sample into the multilayer integrated device,

(e) wherein employing at least one of positive and negative pressure is employed in order to enhance the extraction of the biological sample; and

(f) measuring a characteristic of the biological fluid.

53. (Previously Presented) The method of claim 52 wherein the biological fluid comprises blood.

54. (Previously Presented) The method of claim 52 wherein the biological fluid comprises interstitial fluid.

55. (Currently Amended) An apparatus for obtaining biological fluid for diagnostic testing, said apparatus comprising:

(a) a device for forming an opening in an area of skin suitable for extracting a sample comprising interstitial fluid;

(b) a vacuum device for introducing a vacuum onto the selected area of skin so as to enhance interstitial fluid flow from the skin[,];

(c) wherein the vacuum device is capable of controlling the pressure level and/or timing of the vacuum.

56. (Currently Amended) The apparatus according to claim 55 wherein the vacuum device is capable of being maintained maintaining the vacuum at a desired pressure level.

57. (Currently Amended) An apparatus for obtaining biological fluid for diagnostic testing, said apparatus comprising:

(a) a first device for forming an opening in an area of skin suitable for extracting a sample of biological fluid;

(b) a mechanical second device for introducing a positive pressure to the area of skin to assist in the fluid flow from the opening,

wherein:

(c) the second device is capable of controlling the timing and/or the amount of pressure on the area of skin.

58. (Currently Amended) The apparatus according to claim 57;

(a) further comprising a vacuum device for introducing a vacuum onto the selected area of skin so as to enhance fluid flow from the opening[,];

(b) wherein the second device is capable of controlling the pressure level and/or timing of the vacuum.

59. (Previously Presented) The apparatus of claim 57 wherein the sample comprises blood.

60. (Previously Presented) The apparatus of claim 57 wherein the sample comprises interstitial fluid.

61. (Currently Amended) A method for harvesting biological fluid from tissue and analyzing the biological fluid, said method comprising the steps of:

- (a) placing a layer in contact with a surface of tissue;
- (b) forming at least one hole in the tissue;
- (c) collecting biological fluid from the tissue through at least one opening in the layer that is in fluid communication with the at least one hole in the tissue; and
- (d) wetting a sensor with the biological fluid to measure a characteristic of the biological fluid, wherein the process further comprises; and
- (e) applying positive pressure to the layer so as to induce flow of the biological fluid through the opening.

62. (Currently Amended) A method for harvesting biological fluid from tissue and analyzing the biological fluid, said method comprising the steps of:

- (a) placing a layer having at least one opening therein in contact with a surface of tissue;
- (b) forming at least one hole in the tissue in fluid communication with the at least one opening in the layer;
- (c) collecting biological fluid from the tissue through the at least one opening in the layer; and

- (d) wetting a sensor with biological fluid to measure a characteristic of the biological fluid ~~and wherein the process further comprises the step of;~~ and
- (e) creating a negative pressure ~~to-on~~ the skin surface of tissue so as to induce flow of the biological fluid through the opening hole.

63. (Currently Amended) An integrated fluid harvesting and analysis device, comprising:

(a) a first layer; ~~having~~

(b) a porating element:

(i) disposed thereon ~~on the first layer (a)[,]~~; ~~the porating element~~

(ii) adapted for forming at least one opening in the tissue;

(b)(c) a sensor:

(i) positioned in fluid communication with the at least one opening in the tissue[,]; ~~the sensor being~~

(ii) responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid; and

(e)(d) a mechanical element:

(i) having a small opening therein; ~~and~~

(ii) capable ~~or of~~ receiving the ~~integrated device~~ first layer (a) ~~and the sensor~~

(c) such that the porating element (b) is aligned with the small opening[,]; ~~and the mechanical element~~

(iii) responsive to downward force thereon to cause the surface of the tissue to bulge into the small opening.

64. (Currently Amended) An integrated fluid harvesting and analysis device, comprising:

(a) a first layer having a porating element disposed thereon, the porating element forming at least one opening in the tissue;

(b) a porating element:

(i) for forming at least one opening in tissue;

(ii) disposed on the first layer (a);

(b)-(c) a sensor:

(i) positioned in fluid communication with the at least one opening in the tissue[,]; the sensor being

(ii) responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid, and;

(e)-(d) sealing first means for pneumatically sealing the integrated device first layer

(a) and the sensor (c) to the surface of the tissue and forming a sealed chamber[,]; and

(e) second means coupled to the sealing first means d) for supplying negative pressure to the sealed chamber.